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Federal Water Quality Coalition

July 6, 2015

Mr. Ken Kopocis
Deputy Assistant Administrator
Office of Water
U.S. Environmental Protection Agency (MC4101M)
1200 Pennsylvania Avenue, N. W.
Washington, D.C. 20460

Re: Meeting on Human Health Standards

Dear Ken:

Thank you for taking the time to meet with us on June 19 regarding human health water quality standards issues. As you know, during the meeting we discussed issues regarding the pending proposal to revise Federal recommended human health criteria, as well as EPA's approach to standards being developed in several States, including Washington, Idaho and Maine.

As for the Federal criteria, we appreciate EPA's statement that it has been working to address our concerns. The final Federal criteria were issued last Monday (June 29), and we are reviewing the final criteria and EPA's supporting documents. After that review, we expect to continue our dialogue with OST staff regarding the criteria and the methodology used to develop them.

As for EPA's approach to State standards, we found that the discussion during the meeting helped us to better understand the basis for the Agency's actions. However, we have a number of serious concerns regarding those actions and the basis provided by the Agency. Below, we list those issues and explain our concerns.

Risk Levels and Designation of Target Populations

In its statements regarding the State of Washington's pending standards, EPA has made it clear that it will disapprove those standards if they do not include a Fish Consumption Rate (FCR) of at least 175 grams/day (based on consumption data for certain Tribes) and a 10^{-6} excess cancer risk level. During the meeting, we pointed out that this EPA statement regarding minimum requirements for State

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water quality standards is inconsistent with current Agency policy. That policy provides that it is within States' discretion to establish their own risk levels, as long as they protect the general population within the 10^{-6} to 10^{-5} range, and protect subpopulations at the 10^{-4} level. Requiring a State to protect subpopulations at the 10^{-6} level is not supported by that policy. In response, EPA staff stated during the meeting that due to treaty rights of the Tribes, EPA now views the Tribes as the "target population" – in other words, they are now the "general population" for purposes of human health standards, rather than a subpopulation. We have not seen any legal analysis supporting this position. As explained in comments submitted during the Washington rulemaking (which are attached to this letter), we believe that this use of a "treaty rights" argument to expand EPA's authority under the Clean Water Act is improper, and is inconsistent with court decisions and with claims made by EPA itself in other cases. In any event, even if this new policy is legally supported, there is no question that it is a change in Agency policy, which should not be implemented without a full opportunity for review and comment by stakeholders. Unless and until such a change is made, there is no basis to reject the choice made by the State of Washington to adopt a 10^{-5} excess cancer risk level, which is fully consistent with existing EPA policy and with the State's authority under the cooperative federalism structure that is built into the Clean Water Act.

We also question why EPA is insisting that only a 10^{-6} excess cancer risk level can be adequately protective of public health. The Agency's own policy specifically allows a State to choose either 10^{-6} or 10^{-5}. Moreover, that choice does not make a significant difference in actual risk. The 10^{-6} excess risk level represents a potential increase in baseline cancer incidence of up to 1 case per 1,000,000 population over the course of 70 years, or an annual incidence of up to 0.0143 per 1,000,000 population. The population of the State of Washington in 2014 was about 7.1 million. Therefore, the annual increase in cancers that could conceivably occur – applying the conservative assumptions that every day, everyone eats 175 grams of fish and drinks 2.4 gallons of untreated surface water, and that all of that fish and water is contaminated at the maximum allowed level - would be up to 0.1 case across the entire state population. The corresponding increase at a 10^{-5} risk level – again, applying conservative exposure assumptions - would be up to 1.0 additional case across the entire state population. To put these numbers in context, the existing baseline annual cancer incidence in the State of Washington is more than 38,000 cases. Therefore, the difference in risk between standards set at the 10^{-5} level and standards set at the 10^{-6} level, while mathematically calculable, is simply not significant.

Protection of Downstream Uses

During the meeting, we expressed a concern regarding recent Agency statements, in reviewing State standards, concerning the protection of downstream uses. Of course, existing EPA rules require that those uses be protected. However, in its letters regarding State standards, EPA has been going beyond that policy, implying that the standards of the upstream State need to be at least as stringent as the standards of the downstream State. We see no legal basis for requiring adjacent States to have

identical water quality standards; that would, in essence, Federalize the standards program, which has always been premised on the States having primary authority. In response to our concern, Agency staff stated that EPA has no intent to require identical standards for adjacent States, and that the Agency simply wants to ensure that one State does not jeopardize attainment of standards in another State. We appreciate that clarification. However, we believe that there has been some confusion, and that it would be worthwhile for the Agency to issue a statement clearly laying out its approach on this issue and confirming that upstream States are not required to set water quality standards that are identical to those of downstream States.

Probabilistic Risk Assessment (PRA)

In our discussions with OST staff regarding human health standards over the last several years, we have strongly supported developing these standards based on a probabilistic risk assessment (PRA) approach. As you know, EPA has been using a PRA approach in its pesticides and Superfund program for many years, and the Office of Research and Development has been supporting its use as well. PRA also is a well-accepted means for assessing risks in a number of fields. Just this past August, the EPA Office of the Science Advisor, Risk Assessment Forum issued a White Paper (attached) that did an excellent job of explaining the benefits of a PRA approach and provided a number of case studies where EPA has used a PRA approach to assess risks across a variety of programs.

As you know, several States, including Idaho, are currently developing human health standards using a PRA approach. During our meeting, we asked EPA to explain why it is requiring the State of Idaho to also perform a deterministic analysis to support its standards. Given the widespread use of PRA concepts within the Agency, we see no basis for forcing a State to do both a PRA analysis and a deterministic analysis, when the PRA analysis should be fully adequate to support the standards. (In fact, we believe that a PRA analysis is not only adequate, but is the better way to proceed, since it is based on a more realistic appraisal of the risks posed by the particular parameter.) In response, EPA staff indicated during the meeting that OST is only considering a PRA approach to assess acute risks, and not chronic risks. Staff stated that PRA has mostly been used by the pesticides office for acute risks and that OST questions its applicability to chronic risks. The Agency staff further stated that they want to consider any concerns that the global risk assessment community might have with the use of PRA for chronic effects.

We found those statements concerning PRA very surprising. We are unaware of any reason why expert risk assessment practitioners within EPA or in the global risk assessment community might believe that a PRA approach cannot be used to assess chronic risks. Distribution of exposure characteristics can be developed and assessed in the same manner, whether those exposures are used to derive a chronic standard or an acute standard. Moreover, there is nothing in the EPA White Paper indicating that a PRA approach should be used only for assessing acute risks. In fact, several of the EPA case studies in the White Paper were for chronic risks, including one

assessing the chronic risks of consuming fish contaminated with PCBs; EPA's pesticides office also was involved in 3 of those chronic case studies.

We appreciate the dialogue that we have had with Agency staff concerning the PRA tool, which we made available for their review. We continue to believe that this tool is able to assess both chronic and acute risks, and we look forward to continuing that dialogue, so we can better understand any concerns that the Agency has with the tool or its ability to assess chronic risks. We encourage EPA to confirm that the PRA approach can be used to set water quality standards for both acute and chronic risks, and that a PRA analysis does not need to be supplemented or replaced with a deterministic analysis.

Unattainable Standards

As we stated during the meeting, we are very concerned that EPA's approach toward State human health standards will result in standards that are unattainable, will not result in significant additional public health benefit, and will impose enormous compliance costs on regulated parties. In the State of Washington, for example, studies have shown that if the standards sought by EPA are imposed, facilities could apply the most advanced technology available, resulting in billions of dollars in control costs, and still not be able to meet the resulting CWA permit limits. Moreover, as we indicated in the meeting, our members cannot rely on implementation tools such as variances to provide effective, widespread relief – especially since there are many States where these relief mechanisms have not or will not be used (and will be subject to legal challenges if they are used). What is needed are attainable, science-based standards that can be effectively implemented, and we look forward to working with EPA toward that end.

In conclusion, we would like to thank you again for taking the time to meet with us. We look forward to continued dialogue on these issues with you and your staff.

Sincerely,

Fredric P. Andes
FWQC Coordinator

Cc: Betsy Southerland, Office of Water